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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,339	09/10/2002	Paul Sherwood	13596-003US1	2886

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EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,339	SHERWOOD ET AL.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-14,29-33 and 39-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-14,29-33 and 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Previous Rejections

All previous rejections are withdrawn.

A new ground of rejection follows infra. Since same was not necessitated by Applicant's amendment, this action is NON-FINAL.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-14, 29-33 and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) The phrase "derivative thereof" as used in the claims is a relative term which renders claims 10, 11, 14, 29, 30, 33 and 39-42 indefinite. In particular, "derivative" does not particularly point out the degree or type of derivation that a given compound may have in relation to the parent compound and still be considered a "derivative thereof" as intended by Applicants.[1] Applicants have failed to provide any specific

[1] The only "derivatives" specifically disclosed appear to be salts. Corollary thereto, note that claims 12, 13, 31 and 32 are not subject to this ground of rejection.

definition for this term in the present specification. Lacking a clear meaning of the phrase "derivative thereof", the skilled artisan would not be reasonably apprised of the metes and bounds of the subject matter for which Applicant seeks patent protection.

2) The phrase "injection into the region of an inflamed and painful joint" is a relative term which renders claims 10-14 and 29-33 indefinite. In particular, it is entirely unclear where the "region of an inflamed and painful joint" is precisely, and how far it extends out from the joint *per se*; the specification provides no definition of same.[2] Lacking a clear meaning of the term "region", the skilled artisan would not be reasonably apprised of the metes and bounds of the subject matter for which Applicant seeks patent protection.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-14 and 29-33 rejected under 35 U.S.C. 102(b) as being anticipated by Kunovits (CH682803).

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[2] Note that claims 39-42 have not been rejected on this basis.

The prior art discloses the use of an aqueous solution of 500 mg pantothenic acid (in the form of its calcium salt) to treat osteoarthritis (see the abstract; see also the second paragraph on p. 2). Administrative routes include intramuscular and parenteral (see the penultimate paragraph on p. 1, and claim 3). It is the examiner's position that any injection site used would in the broadest sense be "in the region" of the joint, since that term is indefinite in scope and thus open to subjective interpretation as discussed in subsection "2)" of the "Indefiniteness" section supra.[3]

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

[3] Regarding claims 11 and 30, since any "real-world" population of patients suffering from osteoarthritis would as a statistical inevitability include at least some patients suffering from inflamed knees, hip pain or spinal inflammation, the treatment of those specific conditions is viewed as being inherent in the prior art's disclosure of the condition "osteoarthritis" generally. (Alternatively, one skilled in the art would "immediately envisage" same from that disclosure).

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-14, 29-33 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kunovits (CH682803) in view of Lapin (USP 4,743,596).

The primary reference discloses the use of an aqueous solution of pantothenic acid (in the form of its calcium salt) to treat "disorders treatable with corticosteroids, *e.g.*, neurodermatitis, bronchial asthma, chronic polyarthritis, osteoarthritis, sporting injuries, hay fever and chronic recurrent sinusitis maxillaris" (see the abstract; see also the second paragraph on p. 2). The administration of high doses (500mg) apparently makes this possible by stimulating the endogenous synthesis of corticosteroids. (See the last paragraph of p. 1). The primary reference differs from the instant claims insofar as, although it teaches intramuscular and parenteral administrative routes (see the penultimate paragraph on p. 1, and claim 3), it does not specifically teach injection "into the region of an inflamed and painful joint."

The secondary reference demonstrates what is well-known in the art, namely that acute inflammatory flare-ups of osteoarthritis are best treated by direct injection of corticosteroids into the site of the joint. See col. 2, lines 18-21. Since the secondary reference is cited only to illustrate this general point, it differs from the instant claims insofar as it is silent regarding the use of pantothenic acid.

It would have been obvious to have treated acute inflammatory flare-ups in osteoarthritis patients of the primary reference by injecting 500mg calcium pantothenate directly into the affected joint, since such flare-ups are "disorders treatable by corticosteroids" which are best treated by direct intraarticular injection, as taught by the secondary reference.[4]

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

[4] This would inevitably include the inflamed knees, hip pain or spinal inflammation, *etc.*, required by instant claims 11 and 30, depending on the specific patient and the particular cause of injury. See footnote "3".

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614